REMARKS

In responding to the Office Action, Applicant conducted a telephone interview with Examiner Winkler on July 20, 2004. Applicant thanks the Examiner for the time generously extended for this interview. During this interview, the pending rejection was discussed and the Examiner indicated that data from the human trials may render the present application allowable.

By this amendment, Applicant has canceled claims 5-9, and 17-19 without disclaimer. Applicant reserves the right to pursue claims 5-9 and 17-19 in one or more continuing applications. Claim 20 has been re-written in independent form and includes the elements of claim 19. Support for this amendment can be found in claim 19 and claim 24 as previously filed. Applicant has also amended claims 21 and 22 to depend from now independent claim 20. New claims 25-39 have been added, these claims are directed to treating meningo-encephalitis, or meningitis, encephalitis with interferon alpha-2b. Support can be found in claim 19 as previously filed. Applicant submits that no new matter is added by this amendment. Entry of the amendment, and reconsideration of the application is respectfully requested.

Rejection Under 35 U.S.C. § 103(a)

The Examiner rejects claims 5-9 and 19 under 35 U.S.C. §103(a) as allegedly being unpatentable over Crance (Travaux 1999) in view of U.S. Patent No. 6,387,365, Antiviral Research, 1998 (Takahashi) and Journal of Neurological Science 1999 (Gkecil). Applicant respectfully disagrees with the Examiner's position. Nevertheless, to expedite prosecution Applicant has canceled claims 5-9 and 19. Accordingly, the Examiner's rejection is rendered moot.

Rejection Under 35 U.S.C. § 112, First Paragraph

The Examiner has rejects claims 5, 7-9, 17-24 under 35 U.S.C. §112, first paragraph as failing to comply with the enablement requirement. Applicant respectfully traverses this rejection.

The Examiner takes the position that there is lack of enablement for the administration of interferon alpha-2b by the parenteral route that results in successful treatment of meningitis, encephalitis, or meningo-encephalitis caused by a West Nile virus infection. The Examiner alleges that the disclosure does not overcome the problem cited in the prior art – achieving a high enough concentration of interferon in the brain – unless, as disclosed in Takahashi and Gkecil, it was administered directly into the brain and thus there is lack of predictability and undue experimentation to practice the invention. The Examiner further asserts that the "only real examples" are in cell culture and that the *in vivo* studies are "merely contemplated" (Office Action, Page 5). Applicant respectfully disagrees with the Examiner's position.

To establish a *prima facie* case of non-enablement, the Examiner has the burden of showing that the application does not teach how to make and use the claimed invention. *In re Wright,* 999 F.2d 1557, 1562 (Fed. Cir. 1999). Applicant respectfully submits that the Examiner has not met the burden.

The Examiner refers to Takahashi and Gkecil as exemplifying that the prior art's solution to achieving a high enough concentration of interferon alpha-2b in the central nervous system (CNS) for treatment of sclerosing panencephalitis infection is to administer interferon by the intracranial route. Applicant respectfully directs the Examiner's attention to the fact that both Takahashi and Gkecil are treating viral infections of the CNS caused by the measles virus (see abstract). In contrast, the claims as amended include treating West Nile Virus infection, not the measles virus. One of ordinary skill in the art would not consider the measles virus and treatments thereof interchangeable with treatments of West Nile Virus infections. Different viruses, e.g., Herpes Simplex Virus, HIV, measles are susceptible to different agents. The susceptibility of interferon to measles does equate to susceptibility to WNV. Thus, it is unclear why Takahashi and Gkecil are being cited to support a non-enablement rejection under 35 U.S.C. §112, first paragraph.

With regard to the "real examples" and the "merely contemplated examples" that the Examiner asserts do not meet the enablement requirement, Applicant submits that prophetic examples are allowed if the claimed invention is otherwise disclosed in such a

way as to allow one of ordinary skill in the art to practice the claimed invention without undue experimentation. *In re Borkowski, 422* F.2d 904, 908 (1970) and MPEP 2164.02.

The specification describes, for example, in Example 3 that interferon alpha 2b can be administered at a dose of 3 million units IV initially; 3 million units subcutaneously 12 hours later, then 3 million units subcutaneously every 24 hours for up to 14 days of therapy if tolerated for the treatment of meningitis and/or encephalitis (page 15, lines 14-20). Thus, the specification clearly allows one of ordinary skill in the art to practice the claimed invention without undue experimentation because the dose, route and interval are clearly described for the treatment of West Nile Virus infections.

To further support enablement of the current claims, Applicant submits the Declaration of Dr. James J. Rahal, the inventor of the above-identified application, which describes the results of the clinical trial with interferon alpha 2b using his protocol.

In this clinical trial, 15 patients with evidence of West Nile Virus meningo-encephalitis were treated with interferon alpha 2b, while 8 patients with evidence of West Nile Virus meningo-encephalitis were not treated with interferon. The dose of interferon alpha-2b given to the interferon treated patients was 3 million units IV initially; then 3 million units subcutaneously 12 hours later and then 3 million units subcutaneously every 24 hours for up to 14 days of therapy if tolerated. This is the protocol described at page 15, lines 14-20 of the specification.

In the clinical trial, interferon was **not** given by the intracranial route, which is the route of administration describe by Takahashi and Gkecil for the treatment of the measles virus.

At the end of the clinical trial, it was concluded that interferon alpha-2b treatment for West Nile Virus meningo-encephalitis, which is a combination of meningitis and encephalitis, resulted in significantly improved neurological functional status as compared to patients not given interferon alpha-2b. This equates to the infection resolving and improved neurological outcome in the interferon alpha-2b treated patients. Thus, following the protocol described in the Example 3 of the specification in a clinical trial, it was demonstrated that the claimed invention is effective for treating humans suffering from meningo-encephalitis caused by a West Nile Virus infection.

Applicants respectfully submit that the present application fully enables one of ordinary skill in the art to practice the claimed invention without undue experimentation for treating humans suffering from a meningitis, encephalitis, or meningo-encephalitis caused by a West Nile Virus infection and request that the rejection under 35 U.S.C. §112, first paragraph be withdrawn.

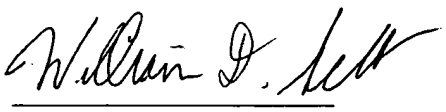
Conclusion

Reconsideration and allowance are respectfully solicited.

Enclosed is the fee for a two-month extension of time. No additional fee is believed to be due with respect to the filing of this amendment. If any additional fees are due, or an overpayment has been made, please charge, or credit, our Deposit Account No. 11-0171 for such sum.

If the Examiner has any questions regarding the present application, the Examiner is cordially invited to contact Applicant's attorney at the telephone number provided below.

Respectfully submitted,



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